CERVIDIL®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or midwife.

1. Why am I being given CERVIDIL?

CERVIDIL can be used to prepare the birth canal in women who require, and have favourable features for, induction of labour after 37 weeks of pregnancy have been completed. It helps the part of the birth canal, known as the cervix, to soften and open to allow the baby through. It contains the active ingredient dinoprostone.

There can be several reasons why you might need treatment with CERVIDIL. Ask your doctor if you would like to know more.

For more information, see Section 1. Why am I being given CERVIDIL? in the full CMI.

2. What should I know before I use I am given CERVIDIL?

CERVIDIL should not be used if you have ever had an allergic reaction to dinoprostone, urethane, or any of the ingredients listed at the end of the CMI.

There are several circumstances in which CERVIDIL should not be used or when it should only be used with additional caution.

Talk to your doctor if you have any other medical conditions or take any other medicines.

For more information, see Section 2. What should I know before I am given CERVIDIL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CERVIDIL and affect how it works. This includes aspirin and other NSAIDs.

Refer to Section 3. What if I am taking other medicines? in the full CMI for more information.

You must not be given CERVIDIL if you are being given, or will be given within the next 30 minutes, other medicines to make your womb contract or bring on (induce) labour, e.g. oxytocin.

4. How will I be given CERVIDIL?

- **CERVIDIL must only be used in a hospital setting by healthcare professionals trained in the care of women and babies during pregnancy and childbirth.** Facilities for continuous monitoring of you and your baby must be available.
- When you are lying down, your doctor or midwife will place one pessary next to the cervix in your vagina.
- The active ingredient dinoprostone will be released from CERVIDIL until it is removed by your doctor or midwife, up to a maximum of 24 hours after it was first given to you.

More instructions can be found in Section 4. How will I be given CERVIDIL? in the full CMI.

5. What should I know while being given CERVIDIL?

Things you should do	• Tell your doctor or midwife if you experience any nausea or vomiting or if you feel unwell in other ways. They may decide to remove the pessary if you have adverse effects.
Things you should not do	• Do not remove the pessary yourself. CERVIDIL should only be inserted and removed by trained healthcare professionals.

For more information, see Section 5. What should I know while using CERVIDIL? in the full CMI.

6. Are there any side effects?

CERVIDIL may contribute to increased or abnormal contractions of the womb, with possible effects on the progress of your labour, or on you or your baby. The effects on you or your baby may depend on the strength of your contractions.

For more information, see Section 6. Are there any side effects? in the full CMI.

Use of CERVIDIL may also contribute to other risks of having labour indued, including heavy vaginal bleeding, inflammation of the membranes lining the inside of the womb, or the risk of a serious condition affecting blood clotting, known as Disseminated Intravascular Coagulation (DIC).

Other side effects can include headache, decrease in blood pressure, itching, swelling or feeling of burning in the genitals, fever, abdominal pain, nausea, vomiting, or diarrhoea. Allergic reactions, including anaphylaxis, have also been reported.

CERVIDIL®

Active ingredient: *dinoprostone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CERVIDIL. **You should also speak to your doctor or midwife if you would like further information or if you have any concerns or questions about being given CERVIDIL.**

Where to find information in this leaflet:

1. Why am I using CERVIDIL?

CERVIDIL comes in the form of a pessary (vaginal insert) and can be used to prepare the birth canal in women who require, and have favourable features for, induction of labour after 37 weeks of pregnancy have been completed. It helps the part of the birth canal known as the cervix to soften and open to allow the baby through. This process is called “Cervical ripening”.

CERVIDIL contains the active ingredient dinoprostone, also known as Prostaglandin E2 or PGE2. Prostaglandin E2 also occurs naturally in the body and is important for the changes that take place during childbirth.

The pessary is held within a pouch attached to a withdrawal tape. Pouch and tape are made of knitted polyester yarn

When placed in the vagina, the pessary takes up some of the moisture there. This allows the active ingredient, dinoprostone, to be released at an appropriate rate until the pessary is removed by your doctor or midwife by pulling the withdrawal tape.

CERVIDIL must only be used in a hospital setting by healthcare professionals trained in the care of women and babies during pregnancy and childbirth. **Facilities for continuous monitoring of you and your baby must be available.**

Your doctor may have prescribed CERVIDIL for another purpose.

Ask your doctor or midwife if you have any questions about why CERVIDIL has been prescribed for you.

2. What should I know before I am given CERVIDIL?

Warnings

Do not use CERVIDIL if:

- you are allergic to dinoprostone, or any of the ingredients (e.g. urethane) listed at the end of this leaflet.
  Always check the ingredients to make sure you can use this medicine.
- you are carrying more than one baby
- there is any reason why you should not have a vaginal delivery, for example, genital herpes or if the placenta is blocking the birth canal
- it is suspected, or tests show, your baby is unwell or not growing
- the head of the baby is too big, or the size of your pelvis is too small for normal delivery
- the baby is not in the normal position for birth
- the baby’s head is not well down in the pelvis
- If you have contractions that are unusually strong and/or long (known as “hypertonic contractions” or “hyper- stimulation of the uterus”).
- you have had previous surgical operation on the womb, for example, a caesarean section *or* surgery to the neck of the womb (cervix) or previous rupture of the uterine cervix
- you have had unexplained vaginal discharge or bleeding during the current pregnancy
- you have untreated pelvic inflammatory disease (also known as PID); usually caused by an infection of the internal female sex organs; it may result in, for example, pain and tenderness of the stomach and fever.
- the packaging is torn or shows signs of tampering or the pessary is missing it’s withdrawal tape, which is used for removal
- after the expiry date (EXP) printed on the pack

Your doctor will not give you CERVIDIL or will remove it after it has been given to you:

- if contractions are considered too sustained or excessive
- Once labour starts
- Prior to amniotomy

- after the waters break (spontaneous rupture of the membranes)
- if there is any suggestion of maternal or fetal complications *or*
- if unwanted side-effects occur, e.g. nausea, vomiting, drop in blood pressure or elevated heart rate
- your doctor wants to use a different medicine to help your womb (uterus) contract e.g. oxytocin
- if after 24 hours the cervix has not changed adequately for delivery

Check with your doctor if you are 35 years or over or younger than 18 years of age or if you have had any medical conditions, especially the following:

- your waters have broken
- your pregnancy is past 40 weeks gestation
- have had more than three full term deliveries
    - previous complications during pregnancy, e.g. low blood pressure, thyroid problems
    - problems with your heart or blood pressure
    - glaucoma (raised pressure in the eye)
    - epilepsy (convulsions or fits)
    - asthma
    - liver, lung or kidney disease
    - gestational diabetes
    - unexplained genital bleeding during current pregnancy
    - abnormally strong contractions of your womb during a previous labour or
    - previous excessively short labour and delivery time
- take any medicines for any other condition (see Section 3. What if I am taking other medicines?

Before CERVIDIL is used, careful assessment of the cervix is necessary.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

CERVIDIL is for women who have a normal pregnancy and are at or near their due date for delivery provided 37 weeks of pregnancy have been completed. It is used to prepare for induction. CERVIDIL should not be used during other phases of pregnancy.

The use of CERVIDIL during breastfeeding has not been investigated. A small amount of the active ingredient in CERVIDIL may pass into breastmilk for a short time but this should not hinder breastfeeding. No effects on the breastfed newborn have been observed.

3. What if I am taking other medicines?

Tell your doctor or midwife if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and CERVIDIL may interfere with each other. You must not be given CERVIDIL if you are being given, or will be given within the next 30 minutes, other medicines to make your womb contract or bring on (induce) labour, e.g. oxytocin.

Medication with aspirin and other non-steroidal anti-inflammatory drugs (known as NSAIDs) should be stopped before administration of CERVIDIL®. Some examples of NSAIDS are Naprosyn and Voltaren.

Tell your doctor or midwife if your have allergies to:

- any other medicines
- any other substances, such as foods, preservatives, or dyes.

Check with your doctor or midwife if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CERVIDIL

4. How will I be given CERVIDIL?

How much you will be given

- CERVIDIL is given as one pessary placed into the vagina once only
- Over the maximum recommended usage period of 24 hours, the insert gradually releases about 0.3 mg of dinoprostone per hour.
- A second dose of CERVIDIL is not recommended, as the effects of a second dose have not been studied.

When you will be given CERVIDIL

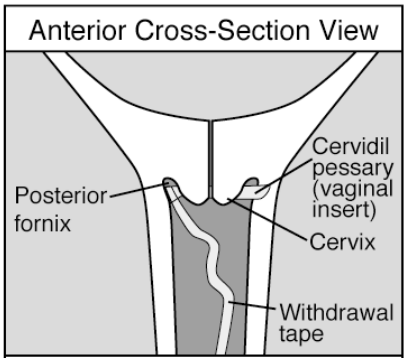
- You will be given CERVIDIL when you have completed at least 37 weeks of pregnancy and before your labour has started.
- CERVIDIL is used to help start the birth process. There can be several reasons why you might need help to start this process. Your doctor may have prescribed CERVIDIL for another purpose.
- Ask your doctor or midwife if you have any questions about why CERVIDIL has been prescribed for you.

How you are given CERVIDIL

- CERVIDIL should be administered only by trained personnel, in hospital, with appropriate obstetrical care and facilities for the required monitoring.
- Your doctor or midwife will coat the CERVIDIL with a little lubricating jelly before putting it in your vagina. The pouch containing the active ingredient is positioned up at the top of the vagina behind the cervix. This is called the “posterior fornix” (See Figure 1).

- Enough of the withdrawal tape will be left outside the vagina. Your doctor or midwife can therefore easily pull out the CERVIDIL pessary when it is time to do so, or if it needs to be removed for any reason

Figure 1



- You will be lying down while CERVIDIL is put in. You should remain lying down for at least 30 minutes afterwards. Your doctor or midwife will advise you when you can get up again.
- When placed in position, the pessary takes up some of the moisture there. This allows the dinoprostone to be slowly released.

When CERVIDIL will be removed

- The pessary (vaginal insert) is removed by gently pulling the withdrawal tape.
- Your doctor or midwife will remove the pessary (vaginal insert) when you no longer need it or after 24 hours.
- For example, they may remove it because:
  - your labour has started
  - your doctor wants to use a different medicine to help your womb (uterus) contract e.g. oxytocin
  - your waters have broken
  - your uterus is contracting too strongly
  - your baby is starting to get distressed.
- After recommended use, when CERVIDIL is removed from the vagina, the tampon-like end will have become larger. It absorbs fluid and becomes 2-3 times its original size.

Overdosage

Your medical attendants will be alert for any signs of overdose. Your doctor or midwife have information on how to recognize and treat an overdose. Initial treatment of overdose is removal of the pessary. Other treatment is also available.

Contact the Poisons Information Centre on 0800 POISON (0800 764 766) for further advice on overdose management.

5. What should I know while using CERVIDIL?

Things you should do

CERVIDIL can be left in place for a maximum of 24 hours depending on your progress. Whilst the pessary remains in place, you will be examined regularly amongst other things for:

- Opening of your cervix
- Uterine contractions
- The continuing health of you and your baby

Tell your doctor or midwife as soon as possible, if you do not feel well while you are being given CERVIDIL. They may decide to remove the pessary if you have adverse effects.

Things you should not do

Do not remove the pessary yourself. CERVIDIL should only be inserted and removed by trained healthcare professionals.

- Looking after your medicine
- CERVIDIL is kept in a freezer and removed immediately before use. It is stored in the hospital.

Looking after your medicine

- CERVIDIL is kept in a freezer and removed from the freezer immediately before use. It is stored in the hospital.

Getting rid of any unwanted medicine

The used pessary (vaginal insert) should be disposed of by the hospital as clinical waste.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or midwife if you have any further questions about side effects.

Tell your doctor or midwife if you notice any of the following and they worry you:

- headache
- dizziness
- itching
- diarrhoea
- fever
- nausea or vomiting

feeling of burning in the genitals

Some side effects can be serious, for example:

- Increased or abnormal contractions of the womb which may or may not affect the baby
- Placenta detaches from the wall of the womb before the baby is delivered
- Heavy bleeding from the vagina following delivery
- Hypersensitivity reaction and severe allergic reactions (anaphylactic reaction), which can include: difficult breathing, shortness of breath, weak or rapid pulse, dizziness, redness of skin and rash

- Disseminated Intravascular Coagulation (DIC), a rare condition which affects blood clotting and can lead to serious bleeding, possibly from multiple sites
- Anaphylactoid syndrome pregnancy, a rare condition caused when the amniotic fluid that surrounds the baby in the womb passes into the mother's bloodstream during delivery and blocks a blood vessel. This can lead to shortness of breath, low blood pressure, anxiety, chills, seizures, coma, bleeding and fluid in the lungs.

Possible effects on your baby:

- Signs of distress, e.g. heart rate faster or slower than normal
- Depressed Apgar score (measures how well the baby is doing immediately after birth)
- Difficulty breathing after birth
- Jaundice (yellowing of skin and eyes)

These are very serious side effects, which can be life-threatening. They need urgent medical attention.

Your doctor and midwife will monitor you and remove the CERVIDIL pessary if your contractions become too strong. If contractions become too strong, there are risks to both the baby, e.g. tearing of the womb and fetal distress which in very severe cases can result in loss of the baby.

Tell your doctor or midwife if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

7. Product details

This medicine is only available with a doctor's prescription.

What CERVIDIL contains

Active ingredient (main ingredient)	Dinoprostone
Other ingredients (inactive ingredients)	The active ingredient is contained in a plastic (polyurethane) sustained release pessary made of: hexanetriol/macrogol 8000 /isocyanate cross-linked hydrogel copolymer.
Potential allergens	Urethane

The pessary is held within a pouch attached to a withdrawal tape. Pouch and tape are made of knitted polyester yarn.

Do not take this medicine if you are allergic to any of these ingredients.

What CERVIDIL looks like

The CERVIDIL® pessary (vaginal insert)

- Is a thin, flat rectangle, with rounded corners
- Is contained within a pouch
- Is made so that, when the pouch becomes moist, the active ingredient (dinoprostone) comes out very slowly. The pouch forms one end of a long tape
- pouch and tape are made of knitted polyester (off-white in colour)
- tape allows withdrawal of the insert at the end of dosing.
- NOTE: After recommended use, when CERVIDIL® is removed from the vagina, the tampon-like end will have become larger. It absorbs fluid and becomes 2-3 times its original size.

Each CERVIDIL insert contains 10mg dinoprostone.

Who distributes CERVIDIL

You can obtain more information from your doctor or midwife.

Sponsor:

Pharmaco (NZ) Ltd
PO Box 4079
Auckland 1140
New Zealand.
Telephone: 09 377 3336

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